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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.,

Plaintiff and Counterclaim-Defendant,

vs.

NATERA, INC,

Defendant and Counterclaim-Plaintiff.

Case No. 21-cv-04062-EMC

NATERA'S TRIAL BRIEF

Pretrial Conference:
Date: June 28, 2023
Time: 3:00 pm
Ctrm: 5 – 17th Floor
Judge: Hon. Edward M. Chen

Trial:
Date: July 24, 2023

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I. INTRODUCTION

Colorectal cancer ("CRC") is a leading cause of cancer death in the United States. Even after initial treatment, some patients still have molecular/minimum residual disease ("MRD") that can cause the recurrence of CRC. MRD refers to the presence of minute amounts of leftover cancer cells from a patient's tumor that can release tumor DNA into the bloodstream (i.e. circulating tumor DNA, or "ctDNA"). Early and accurate detection of MRD allows doctors to timely prescribe the appropriate treatments to the right patients, with the goal of preventing recurrence and saving lives.

Natera, Inc. ("Natera") is a global leader in cell-free DNA (cfDNA) testing and a leading provider of diagnostic tests for MRD detection. Natera's Signatera™ is a one-of-a-kind bespoke diagnostic test that creates a personalized blood test for each patient. It relies on genetic mutations found in a patient's own tumor tissue to detect tumor DNA in the patient's blood samples. Signatera builds on Natera's pioneering cell-free DNA detection platform and technology, which it originally deployed in the women's health context. First available for research use in 2017, Signatera was launched for clinical use in May 2019. Signatera's accuracy and reliability has been demonstrated in many peer-reviewed publications in highly-regarded scientific journals, including a landmark study published in 2019 ("the Reinert Study"), as well as in prospective clinical studies on thousands of CRC patients, such as the CIRCULATE study.

Although Guardant Health, Inc. ("Guardant") has a longer history than Natera in oncology, it is a relative newcomer to cfDNA and MRD detection. In February 2021, Guardant commercially launched its own MRD test for CRC called Reveal™ for clinical use. Unlike Signatera, Reveal does not use tissue, is not personalized to each patient, and instead relies on looking for standard CRC mutations and a secondary signal called methylation to detect MRD. Reveal lags behind Signatera, in both performance and peer-reviewed data. Stuck playing catch-up with inferior technology, Guardant engaged in false advertising of Reveal, purportedly based on the sole peer-reviewed study published in 2021 ("the Parikh Study") which Guardant co-authored. When Natera expressed its concerns about Guardant's false advertising—in particular its false clinical performance claims for Reveal—Guardant brought this case to silence Natera's legitimate speech and to shield Reveal's true performance from criticism. In response, Natera filed counterclaims against Guardant.

[redacted]

The central dispute in this case is whether Guardant's and Natera's statements regarding their own and each other's products are false, and whether the intended audience (oncologists) were deceived. Both parties cited published, peer-reviewed data in their advertisements. However, only one party—Guardant—used its influence to manipulate the methodology and data of its cited study (the Parikh Study) behind the scenes, and then hid those actions. For example, despite the Parikh Study's claim that it was a "prospective" study with analysis performed "blinded" to clinical outcome, discovery has exposed that Guardant accessed ***unblinded*** data, which it used to ***retrospectively*** re-analyze data—all for the purpose of making Reveal's performance appear better than it really is. These facts prove the Parikh Study to be wholly unreliable, and render Guardant's advertising claims based on that study literally false. Not only that, but many of Guardant's claims lack support in the Parikh Study and are literally false for that alternative reason. In contrast, Natera's advertisements report data that are literally true (as this Court has ruled on summary judgment), and there is no evidence any physician was misled by them.

II. BACKGROUND

Natera's Signatera is a personalized, bespoke ctDNA test designed to detect MRD in patients previously diagnosed with cancer, to aid detection of cancer recurrence. Signatera's technology analyzes sequencing data from a patient's tumor sample to custom design patient-specific assays, targeting mutations known to be present in the patient's tumor tissue, to detect those mutations in the patient's blood plasma samples. This uniquely personalized "tumor informed" approach to blood testing enables physicians to accurately detect and monitor the presence of ctDNA, well before recurrence would be detected by the standard of care.

Signatera has been used by thousands of patients in the clinical setting, in one of two ways: (1) testing right after surgery to assess the need for adjuvant therapy (i.e., adjuvant setting); or (2) testing for recurrence monitoring (i.e., surveillance setting). The surveillance setting involves testing patients of unknown recurrence status with repeated blood draws on a regular schedule for the months and years following treatment.

Since 2020, Signatera has been fully covered by Medicare for both adjuvant and surveillance uses in CRC patients. It has also been granted three Breakthrough Device Designations by the FDA

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for different types of cancers. Signatera's performance has been analytically and clinically validated as being a highly sensitive and specific test in multiple cancer types including CRC, non-small cell lung, breast, and bladder cancers, as demonstrated in many peer-reviewed publications in highly regarded journals, such as the Reinert Study, and several large prospective clinical studies involving thousands of patients, such as the CIRCULATE study.

In February 2021, Guardant launched Reveal, a "tumor naïve" MRD test that Guardant hoped to compete with Signatera. Like Signatera, Reveal is a ctDNA test, designed to detect the presence of MRD in patients previously diagnosed with CRC. But, unlike Signatera, Reveal is not personalized. It is a "tumor naïve" test (as opposed to "tumor-informed"), meaning that it does not incorporate any data from the patient's own tumor tissue—instead it tests blood samples from all patients for the same standard mutations and DNA modifications (methylation), not specific to each patient. Reveal has not been granted any FDA Breakthrough Device Designation. Reveal received partial Medicare reimbursement in August 2022, but not for recurrence monitoring (surveillance).

III. LEGAL STANDARD

To succeed on a false advertising claim under Lanham Act § 43(a),[1] a party must prove:

> (1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by lessening of the goodwill associated with its products.

Wells Fargo & Co. v. ABD Ins. & Fin. Servs., Inc., 758 F.3d 1069, 1071 (9th Cir. 2014); *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139-40 (9th Cir. 1997) (law on false advertising establishment claims). Literally falsity creates "a presumption of deception and reliance." *Nat'l Prod., Inc. v. Gamber-Johnson LLC*, 699 F. Supp. 2d 1232, 1237 (W.D. Wash. 2010).

[1] The parties' false advertising and unfair competition claims under California law are "substantially congruent" to the Lanham Act claims.

[redacted]

IV. ARGUMENT

A. Guardant engaged in false and misleading advertisements on Reveal.

Guardant has falsely and misleadingly mispresented critical clinical performance metrics of Reveal, such as sensitivity (a measure of an assay's ability to detect true positives and avoid false negatives), specificity (a measure of an assay's ability to detect true negatives and avoid false positives), and positive predictive value ("PPV") (a measure of the proportion of patients with positive test results who actually have the disease).

Guardant's clinical performance advertising claims for Reveal are purportedly based on a single published study—the Parikh Study, led by Drs. Aparna Parikh and Ryan Corcoran of Massachusetts General Hospital ("MGH") and published in *Clinical Cancer Research* in 2021. That the Parikh Study was peer-reviewed and ultimately published in a scientific journal does not absolve Guardant—a co-author of the study and independently responsible for running all of the tests on patient samples[2]—of liability for its false and misleading *commercial statements* regarding Reveal.

Natera's false advertising claims against Guardant are based on two distinct theories of literal falsity under *Southland*, 108 F.3d at 1139. Under the ***first*** theory ("***unreliability theory***"), literal falsity of advertising claims based on a study can be proven by showing the study is "not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim[s] made." *Id.* at 1139 (internal quotation marks omitted). This showing can, in turn, be made by "attacking the validity of the defendant's tests directly." *Id.* Under the ***second*** theory ("***lack-of-support theory***"), literal falsity of advertising claims can be proven by showing the study, "even if reliable, do[es] not establish the proposition asserted by the defendant." *Id.*

Either theory of literal falsity is sufficient to impose liability on Guardant.[3] *First*, under the unreliability theory, Natera contends the Parikh Study is based on fraud and inaccurate description.

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[2] The Parikh Study names five Guardant employees including its co-founder, Dr. Talasaz, as authors. The Guardant authors were intimately involved with nearly all aspects of the study.

[3] Natera also asserts that Guardant's advertising regarding Reveal, even if "not literally false," is misleading, which imposes liability on Guardant, and Natera will show that "the advertisement has misled, confused, or deceived the consuming public." *Southland*, 108 F.3d at 1140. Evidence that advertising deceived or had a tendency to deceive consumers can be established by "direct evidence," *U-Haul Int'l Inc. v. Jartran, Inc.*, 793 F.2d 1034, 1041 (9th Cir. 1986), or via expert testimony, *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256 (11th Cir. 2004).

[redacted]

In particular, the Parikh Study's false claims of being performed "blinded" and being a "prospective" study—render it wholly unreliable. *Second*, under the alternative lack-of-support theory, Natera contends Guardant's advertisements make claims about Reveal's performance that cite the Parikh Study, but are not supported by the Parikh Study, or any other study. Rather, Guardant's performance claims for Reveal distort and mischaracterize the findings of the Parikh Study—*e.g.*, claiming the study established Reveal's clinical performance in the surveillance setting when it did not. Thus, those claims are not and cannot be established by the Parikh Study, even assuming the study were reliable, rendering them literally false.

ONY, Inc. v. Cornerstone Therapeutics, Inc., 720 F.3d 490 (2d Cir. 2013), which the Court has found applies in this case,[4] does not foreclose Natera's claims. In *ONY*, the Second Circuit held that where "a speaker or author draws conclusions from ***non-fraudulent data***, based on ***accurate descriptions of the data and methodology*** underlying those conclusions," their statements are "not grounds for a claim of false advertising."[5] *Id.* at 498. Here, Natera contends that the Parikh Study and Guardant's advertisements are based on ***fraudulent*** data and ***inaccurate description*** of the data and methodology of the Parikh Study. Moreover, *ONY* expressly acknowledged that it does not address a scenario involving a party—like Guardant here—distorting a study's findings in its advertising. 720 F.3d at 499 ("We are therefore presented with a much easier case than we would be if a plaintiff alleged that a defendant distorted an article's findings in its promotional materials.").

Indeed, in denying Guardant's motion to dismiss Natera's counterclaims, this Court held that "*ONY* excepted from this general rule of deference disputes about statements made in a peer-reviewed, published study that are 'literally false,' *i.e.*, where the study at issue was 'fabricated' or 'fraudulently created.' Courts can resolve these kinds of disputes because if 'the data were falsified, the fraud would not be easily detectable by even the most informed members of the relevant scientific community.'" Dkt. 120 at 10 (quoting *ONY*, 720 F.3d at 497). And, where "false advertising claims allege that the study's conclusions are based on inaccurate descriptions of the data and methodology, the claims are actionable under the Lanham Act." *Id.* at 20. The Court also

[4] Natera does not concede that *ONY* was correctly applied or is the law in this circuit.
[5] Emphases added herein unless otherwise noted.

[redacted]

held that "*ONY* is inapplicable to Natera's counterclaims that allege that Guardant's statements are unsupported by the Parikh Study." *Id.* at 12.

1. Natera's unreliability theory: Guardant's advertising claims for Reveal are not established because the Parikh Study is unreliable.

Guardant manipulated the methodology and data reported by the Parikh Study and then concealed its actions, rendering the Parikh Study unreliable and fraudulent and Guardant's reliance on it literally false. For example, the Parikh Study fraudulently claims: (1) to have been a fully "prospective study" when its analyses were retrospective; and (2) that its analysis was performed "blinded" to clinical data when Guardant used unblinded data for the analyses.

(a) The Parikh Study falsely and fraudulently describes itself as a "prospective" study.

The Parikh Study purports to be a "prospective" study. TX-0002.0002. Conducting a "prospective" study according to a pre-established protocol provides a significant indicium of reliability as compared to a retrospective study without a pre-established protocol where decisions are made after the outcome of interest (here, recurrence) is known. However, the Parikh Study failed to follow *any* pre-established protocol for ctDNA analysis and instead *retrospectively* analyzed samples to evaluate performance metrics for Reveal. Guardant's own documents establish that the Parikh Study authors, including Guardant, eschewed any pre-established protocol in favor of *post hoc* methods and analyses that could be manipulated to tell different "stor[ies]." TX-3124.0002. Guardant's witnesses confirmed at deposition that the Parikh Study's analyses were retrospective.

(b) The Parikh Study falsely and fraudulently describes itself as "performed blinded to the clinical data."

The Parikh Study reported that "ctDNA analysis was performed blinded to the clinical data." TX-0002.0003. Conducting a study according to a "blinded" protocol is another significant indicator of reliability. However, Guardant had access to the patients' recurrence status for the samples it was analyzing, rendering it unblinded. Guardant has now admitted, only after this litigation commenced, that the Parikh Study was unblinded. Dkt. 94-4 at 19 (conceding "[t]he [Parikh Study] data were partially unblinded before final analysis").

[redacted]

As a result, at the time Guardant was analyzing (and subsequently reanalyzing) samples to generate results for inclusion in the study, it already had the answer key as to which patients had experienced recurrence. Guardant therefore knew, for example, whether running additional samples would help or hurt performance. The evidence shows it took full advantage of this knowledge, for example, by analyzing samples ***only*** from recurring patients who had prior false negative results knowing they "can only improve the sensitivity for recurrence." TX-0978.0001. Guardant witnesses confirmed that it performed its ctDNA analysis ***unblinded*** to clinical data. This analysis included [redacted][6]—with full knowledge of recurrence status.

Using unblinded data and passing off the study as blinded is fraud. Nitin Sood, former Reveal product lead, admitted that "if the bioinform[atics] that's calling ctDNA positive or not positive is aware of the outcome already, that would not be fair." Sood Tr. at 307:8-16. Guardant's expert Dr. Heitjan went further, stating that those who falsely claim a study was blinded when it is not should be put in "scientific jail." Heitjan Tr. at 302:12-22.

(c) The Parikh Study includes additional inaccurate descriptions.

In addition to the fraudulent claims above, the Parikh Study includes additional inaccurate descriptions of its own methodology that render the study unreliable. In particular, the Parikh Study defines its analyses in certain ways, but does not actually follow those definitions such as claiming "landmark" samples were taken "approximately 1 month" after treatment, TX-0002.0002, when the study falsely includes samples taken many months later.

These falsehoods demonstrate that the Parikh Study is unreliable. They render all of Guardant's claims based on the Parikh Study literally false.

Guardant's position that peer review of the Parikh Study immunizes the study from criticism and its advertising statements from liability is at odds with the case law (Dkt. 120 at 10, 12, 20), and would only reward its deceptions. That the peer reviewers were unable to observe or detect Guardant's machinations makes them ***more*** egregious not less. Evidence also shows that the Parikh

[6] [redacted]

[redacted]

Study was repeatedly rejected by other journals; that [redacted]. Peer review provides no safe harbor for Guardant. !

2. Natera's lack-of-support theory: Guardant's advertising claims for Reveal are not established because they are not supported by the Parikh Study, even if the study were considered reliable.

Even taking the Parikh Study at face value, Guardant's advertising is false and misleading for the additional, independent reason that it includes claims that cannot be established by the Parikh Study. Under *Southland*, the second way to show literal falsity is not to attack the study itself, but show that there is no support in the study for the claims made in the advertisements. Trial will demonstrate that at least the following claims have no support in the Parikh Study.

(a) Guardant's advertising that Reveal has "91% sensitivity in the surveillance setting" is not supported by the Parikh Study.

Guardant's marketing has repeatedly touted the 91% sensitivity in the "surveillance" setting for Reveal. *E.g.*, TX-0086.0006; TX-0086.0008; TX-0089.0001; TX-0163.0002; TX-3182.0006; TX-0159.0017; TX-0082.0003. But Guardant's internal documents admit that the Parikh Study's definition of "surveillance" is [redacted] TX-0099.0005, TX-0111.0015, and at odds with Guardant's own clinical recommendation for "surveillance" in its marketing of Reveal, *e.g.*, TX-0086.0014, TX-3182.0003. Dr. Parikh confirmed the study did not evaluate Reveal in the context of Guardant's surveillance program or establish *any* clinical performance in that setting. Internal documents show Guardant knows that [redacted].

(b) Guardant's advertising that Reveal has "100% specificity in the surveillance setting" is not supported by the Parikh Study.

Guardant's advertising falsely claims Reveal has 100% specificity in the surveillance setting.

[redacted]

E.g., TX-0080.0008. But the Parikh Study reported no "surveillance" specificity. [redacted] This claim is additionally false because it tells physicians Reveal has no false positives, [redacted] TX-3701.0009.

(c) Guardant's advertising that Reveal has "100% PPV" is not supported by the Parikh Study.

As with the 100% specificity claim, the 100% PPV claim is false as it tells physicians Reveal has no false positives. Guardant witnesses admitted that this metric was achieved only by [redacted] to retrospectively exclude two potential false positive patients who would otherwise negatively impact the PPV. TX-0150.0006. None of Guardant's at-issue advertisements discloses this material information.

(d) Guardant's pairing of sensitivity and specificity from different analyses is not supported by the Parikh Study.

Guardant reported performance metrics from different Parikh Study analyses as if they were from the same analysis in its advertising. *E.g.*, TX-0159.0017; TX-0080.0008. This presents a false view of test performance. Nothing in the Parikh Study supports this conflation of disparate analyses. Sensitivity and specificity must be reported from the same cohort and analysis to be meaningful; mixing and matching them as Guardant has done here will not reflect the test's actual performance ***in any context***. Guardant's sleight-of-hand also falsely suggests a specificity for the surveillance analysis when there is none. TX-0105.0001; TX-3473.0002.

(e) Guardant's advertising that Reveal has superior performance relative to CEA is not supported by the Parikh Study.

Guardant relied on the Parikh Study to compare aspects of Reveal's performance to the

[redacted]

standard-of-care carcinoembryonic antigen ("CEA") test. *E.g.*, TX-0086.0006; TX-0092.0012. Guardant falsely claims Reveal detects recurrence "months earlier" than standard-of-care methods like CEA tests. TX-0082.0003; TX-0086.0006; TX-0092.0012. But the Parikh Study reported ***no data*** that would permit a determination of the lead time of CEA in the Parikh Study patients. Guardant also falsely claims Reveal has "a higher . . . specificity than CEA . . . in the surveillance setting." TX-0082.0003. [redacted]

(f) Guardant's advertising that Reveal has "industry-leading sensitivity" is not supported by the Parikh Study.

The unsupported 91% sensitivity claim, discussed above, formed the basis of Guardant's false advertising of "industry-leading ***sensitivity***" for Reveal. TX-0159.0019; TX-0910.0001. When asked whether Reveal has superior clinical sensitivity to Signatera, Dr. Parikh testified that the Parikh Study does not establish that. Other Guardant witnesses agreed.

(g) Guardant's performance claims regarding Reveal in "early stage" CRC patients are not supported by the Parikh Study.

Although Reveal is intended for ***early stage*** (Stage II-III) patients, Guardant's advertising of Reveal reports data from the Parikh Study that are from all CRC patients, including late stage. *E.g.*, TX-0082.0002; TX-0086.0001; TX-0086.0002; TX-0086.0006; TX-0910.0001. And 19% of the patients studied in the Parikh Study were ***late stage*** (Stage IV) patients. TX-0002.0004. Dr. Parikh confirmed the Parikh Study did not achieve validation of Reveal in early-stage cancers. Guardant recognized this limitation of the study. TX-0005.0002; TX-3240.0001; TX-0259.0002 [redacted]. Yet Guardant still falsely claimed in its marketing that the Parikh Study represents Reveal's performance in the intended-use population. TX-0080.0006.

Guardant has therefore made numerous false statements about Reveal's performance in its advertising, each of which represents a separate establishment claim Natera can prevail on at trial. Dissemination of these statements regarding Reveal's performance—including the baseless claims about its performance in the surveillance setting—misleads patients and physicians into believing Reveal's performance is better than it actually is, a crucial consideration for physicians when

[redacted]

deciding whether to choose Reveal for patients. This puts Natera at a competitive disadvantage and endangers patients whose physicians rely on MRD testing to guide cancer treatment.

3. All the other elements of Natera's claims against Guardant are met.

Evidence establishes all the other elements of Natera's Lanham Act false advertising claims against Guardant—deception, materiality, and injury. As discussed above, Guardant's advertising regarding Reveal is literally false because the Parikh Study does not establish or support any of Guardant's at-issue advertising statements regarding Reveal. Guardant's literally false advertising of Reveal creates "a presumption of deception and reliance." *Nat'l Prod.*, 699 F. Supp. 2d at 1237. Moreover, as discussed below with respect to damages, evidence of Natera's injury is strong and credible, based on actual spending by Natera on corrective advertising.

B. Natera's advertising statements accurately reported data from the cited studies and are not false or misleading.

Unlike Guardant's advertisements, this Court has already found that Natera's advertisements accurately cited data from published studies and thus are literally true. As this Court recognized in its summary judgment order: "Here, all Natera's advertising statements at issue are directly derived from the Reinert study and the Parikh study. The numbers are not literally false on their face." Dkt. 326 at 13. The crux of Guardant's false advertising claim is in essence that, while it is ***true*** the study data showed higher performance for Signatera versus Reveal in certain metrics, it is nevertheless misleading to imply Signatera is therefore superior because there were certain differences between the studies. Guardant attempts to invoke the "literally false by necessary implication" doctrine to blur the important lines between the two theories of false advertising—literally false versus misleading. But as explained in Natera's *Motion in Limine* No. 1, the "by necessary implication doctrine" is a limited subspecies of literal falsity and does not apply to the facts in this case. As described in Natera's *Motion in Limine* No. 1, the "apples to oranges" line of cases apply to comparison of different ***products***—not comparison of rival products as in this case. Regardless, ample evidence, including testimony from numerous Guardant witnesses, demonstrates that Natera's advertisements are neither literally false nor misleading to physicians.

[redacted]

1. Natera's advertising statements are literally true.

Guardant's expert Dr. Heitjan testified that Natera's advertising accurately reports the cited study data. Numerous other Guardant witnesses likewise admitted Natera's advertising accurately reports various performance metrics from the cited studies:

- **Pre-surgical detection:** Guardant admits Natera's advertisements accurately reported pre-surgical sensitivity of 88.5% (Signatera) and 47% (Reveal).
- **Lead time:** Guardant admits Natera's advertisements accurately reported lead time of 8.7 months for Signatera (based on the Reinert Study) and ~4 months for Reveal (based on the Parikh Study), the latter of which Guardant agrees is "the best source for determining a lead time for Reveal."
- **Failure rate:** Guardant admits Natera's advertisements accurately reported the failure rate from the study data at 3% combined tissue and plasma for Signatera (based on the CIRCULATE study) and 12-14% for Reveal (based on the Parikh Study).
- **NPV/PPV/HR:** Guardant admits Natera's advertisements accurately reported the NPV, PPV, and hazard ratios of Signatera and Reveal based on the cited studies.
- **Longitudinal sensitivity:** Guardant admits Natera's advertisements accurately reported the serial longitudinal sensitivities of Signatera (88%) and Reveal (69%).

Without evidence of facial literal falsity, Guardant argues the comparisons between two different studies are false by implication (i.e., misleading). But Guardant witnesses confirmed there is nothing wrong with making performance comparisons between the Parikh and Reinert Studies, and [redacted]. TX-0152.0002-0006; TX-0255.0007; TX-0951.0006; TX-0994.0001; TX-3032.0024-0026, TX-3034.0015; TX-3035.0001. Indeed, the Parikh Study was designed to be directly comparable to the Reinert Study. TX-3607.0020; TX-3036.0001.

2. Guardant cannot show actual deception from Natera's advertising.

As described in Natera's Motion *in Limine* No. 1, because Natera accurately reported the study data in its advertising, and thus its advertising is not literally false, there is no presumption of deception available to Guardant. And Guardant cannot prove actual deception resulting from Natera's ads. It has no evidence any physician ordering the parties' assays was misled. Its witnesses have testified that physicians are "highly knowledgeable" and sophisticated people, driven to adopt new assays by "evidence" such as published studies. And, as discussed below and in Natera's

[redacted]

Motion *in Limine* No. 5, Guardant's litigation survey is unreliable and, in any event, does not show any deception. Guardant's other expert Dr. Heitjan cannot fill in this evidence gap, as he admitted he is "not expressing opinions about the opinions of medical oncologists."

3. Guardant cannot show Natera's advertising was likely to influence any physician decisions.

Guardant's witnesses admitted that, [redacted] and that physicians are "highly knowledgeable" people, driven to adopt new assays by "evidence" such as published studies. The evidence thus shows physicians are ***unlikely*** to make ordering decisions based on Natera's advertisements, as opposed to the underlying data. And Guardant cannot show materiality, as its survey expert did not test the impact of any marketing claims on physician decisions. *Pfizer, Inc. v. Miles, Inc.*, 868 F. Supp. 437, 455 (D. Conn. 1994) ("Miles has failed to establish that Pfizer's use of a cross study comparison of [two studies] is actionable as either a literal falsity or misleading representation," as "***physicians are presumably aware of the inherent limitations in cross study comparisons***").

4. Guardant's litigation survey is flawed.

Guardant's survey is highly flawed and its survey expert's opinions are unlikely to be found credible. Guardant's survey tested the wrong questions and failed to account for pre-existing beliefs about the parties' respective tests. To the extent the survey has any bearing on the issues at all, it shows that physicians believe Signatera to be superior to Reveal based on their own experience, not Natera's advertising.

Guardant will attempt to claim there is some evidentiary void because Natera did not conduct its own survey, but literally false claims like the establishment claims Natera asserts are presumed deceptive. Moreover, this argument disregards the fact that "nothing in the Lanham Act, nor under [9th Circuit] precedents, requires a plaintiff to use such surveys.'" *Youngevity Int'l v. Smith*, No. 16-CV-704-BTM-JLB, 2019 WL 2918161, at *3 (S.D. Cal. July 5, 2019). Here, Natera did not need a litigation survey, which often comes with inherent skepticism, because market research *performed by Guardant* in the normal course of business demonstrates that consumers were actually

[redacted]

deceived by Guardant's false and misleading statements, which it characterized as the "key selling messages" for Reveal.. This compelling evidence shows that Guardant knowingly spread false and misleading claims about Reveal's performance.

5. Guardant cannot show actual injury from Natera's advertising.

The record is replete with evidence showing a ***lack of harm*** to Guardant, as opposed to its presence. For instance, Guardant's executives have stated publicly in earnings calls about how "very pleased" they have been with Reveal sales and that it has exceeded their expectations. Guardant will be unable to show any actual injury of likelihood thereof at trial.

C. Guardant's damages seek a legally impermissible windfall, whereas Natera's damages are reasonable and fully supported by law.

1. Natera's damages theory is reasonable and credible.

Natera incurred substantial corrective advertising expenditures related to Guardant's false statements--conservatively [redacted] Natera's damages expert, Dr. Stec vetted Natera's calculations and downward adjusted that amount to [redacted]

2. Guardant's damages theory is speculative and unreliable.

Guardant claims: [redacted] in prospective corrective advertising costs; [redacted] in lost profits; and [redacted] in disgorgement—each of these is speculative and unreliable.

[redacted] ***in future corrective advertising***. Although Guardant has not undertaken any corrective advertising efforts to date, Guardant's expert Malackowski opines it will need to spend [redacted] on corrective advertising at some point in the future. He gets to this number by [redacted] No authority supports this "methodology."

[redacted] ***in lost profits***. Guardant [redacted] Nonetheless, Malackowski opines that Guardant [redacted] He did not undertake *any* analysis to vet the reliability or reasonableness of this rosy projection before blindly relying on it. This projection is based on unreasonable assumptions and it deviates materially from other projections Guardant

[redacted]

produced (that he never considered).

Disgorgement. Malackowski offers two numbers for disgorgement damages. [redacted]. He does not deduct any other incremental costs that Natera undisputedly incurred. The Lanham Act disgorgement remedy is for "profits," but his high scenario is undisputedly just revenues and his "low" scenario does not deduct all costs that are required to be deducted, such as commissions, which are a quintessential variable cost. [redacted] There is nothing to disgorge.

[redacted]

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Respectfully submitted,

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By */s/ Kevin P.B. Johnson*
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